

Exhibit C

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products
Liability Litigation,

No. MDL15-2641-PHX-DGC

Doris Jones, an individual,

Plaintiff,

v.

C. R. Bard, Inc., a New Jersey corporation;
and Bard Peripheral Vascular, Inc., an
Arizona corporation,

Defendants.

PLAINTIFF'S PROPOSED JURY INSTRUCTIONS NOT AGREED TO

DATED: May 1, 2018

David G. Campbell
United States District Judge

PLAINTIFF'S PROPOSED INSTRUCTION STRICT LIABILITY DESIGN

Mrs. Jones contends that Bard is strictly liable because of a defective design of the Eclipse IVC filter.

The manufacturer of a product that is sold as new property may be liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product. However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable. To recover damages for strict product liability based on a design defect, Mrs. Jones must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

Second, the design defect existed at the time the product left the control of Bard; and

Third, the design defect in the product was a proximate cause of Mrs. Jones' injury.

There is not a single general way to define what constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on the instruction that I will give you and the evidence that has been received during the trial.

Although Bard is not required to ensure that a product design is incapable of producing injury, it has a duty to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

- 1) the usefulness of the product;
- 2) the severity of the danger posed by the design;
- 3) the likelihood of that danger;
- 4) the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger;

- 5) the user's ability to avoid the danger;
- 6) the technology available when the product was manufactured;
- 7) the ability to eliminate the danger without impairing the product's usefulness or making it too expensive;
- 8) the feasibility of spreading any increased cost through the product's price;
- 9) the appearance and aesthetic attractiveness of the product;
- 10) the product's utility for multiple uses;
- 11) the convenience and durability of the product;
- 12) alternative designs of the product available to the manufacturer; and
- 13) the manufacturer's compliance with industry standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Mrs. Jones' injury. In determining the reasonableness of the product design chosen by Bard, you should consider:

- 1) the availability of an alternative design at the time Bard designed this product;
- 2) the level of safety from an alternative design compared to the actual design;
- 3) the feasibility of an alternative design, considering the market and technology at the time the product was designed;
- 4) the economic feasibility of an alternative design;
- 5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and
- 6) any adverse effects on Bard or the product from using an alternative design.

If you decide that the risk of harm in the product's design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design, and the product is defective. If after balancing the risks and utility of the product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Mrs. Jones' injury, then Mrs. Jones is entitled to recover damages.

Defendants' Objections:

Bard objects to Plaintiff's proposed charge because she has deleted two necessary elements from this instruction as given in *Booker*. First, Plaintiff deleted the paragraph that refers to considering compliance with industry standards or government regulations, which is an element of the risk utility test set forth by the Georgia Supreme Court, and for which a separate jury instruction was created. See, Ga. Civil Pattern Instruction 62.670 below:

62.670 Strict Liability; Design Defect; Compliance with Industry Standards or Government Regulations

In determining whether a product was defective, you may consider proof of a manufacturer's compliance with federal or state safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

Banks v. ICI Americas Inc., 264 Ga. 732 (1994)

Doyle v. Volkswagenwerk Artiengesellschaft, 267 Ga. 574 (1997)

Second, Plaintiff also deleted the paragraph regarding regulatory action. However, under Georgia law when a plaintiff claims a design defect in a widely-distributed product, "[t]he fact that . . . [defendant] had never been subjected to regulatory action with respect to the claimed defect . . . tends to negate the allegation that the configuration was a dangerous design." *Browning v. Paccar, Inc.*, 214 Ga. App. 496, 498, 448 S.E.2d 260, 263 (1994). As such, "evidence that the customary methods for protecting the public from defective [products] had not been instituted in connection with these [products] was relevant to show defendant's design and manufacture was not negligent." *Id.*

Defendants' proposed alternative is Defendants' Instruction on Design Defect

Plaintiff's Response:

For the reasons stated in Booker, Bard's proposed language provides undue emphasis on FDA evidence, drawing the jury's attention to FDA actions and inactions on three separate occasions. This results in an emphasis or comment on certain types of evidence as more important than other factors.

PLAINTIFF'S PROPOSED INSTRUCTION NEGLIGENT DESIGN

Mrs. Jones claims that Bard was negligent in the design of the Eclipse IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

- (1) Bard had a duty of reasonable care to Mrs. Jones,
- (2) Bard breached that duty in the design of the Eclipse filter,
- (3) the breach was a proximate cause of Mrs. Jones' injury, and
- (4) she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in the design of the Eclipse filter she received.

Defendants' Objections:

Defendants acknowledge that Plaintiff's proposed instruction is the same as the one given in *Booker*. However, Defendants object to this instruction on the grounds that it does not comply with Georgia law. See, *Ogletree v. Navistar International Transportation Corporation*, 271 Ga. 644 (1999), in which the Georgia Supreme Court held, "In a negligent design case, the risk-utility analysis applies to determine whether the manufacturer is liable. Thus, the mandate that a product's risk must be weighed against its utility incorporates the concept of 'reasonableness' so as to apply negligence principles in the determination of whether the manufacturer defectively designed its product." (Citations omitted)

Defendants' proposed alternative is Defendants' Proposed Instruction on negligent design.

Plaintiff's Response:

Plaintiff believes the instruction given in Booker was appropriate and avoids undue comment on the evidence of risk-benefit, which is but one of many factors a jury may consider in examining the evidence.

PLAINTIFF’S PROPOSED INSTRUCTION NEGLIGENT FAILURE TO WARN

Mrs. Jones claims that Bard was negligent in failing to warn about the risks of the Eclipse IVC filter she received. To recover on this claim, Mrs. Jones must prove by a preponderance of the evidence that:

- (1) Bard had a duty of reasonable care to Mrs. Jones (via warnings to her physicians),
- (2) Bard breached that duty in the adequacy of the warnings about the Eclipse filter,
- (3) the breach was a proximate cause of the her injury, and
- (4) she suffered damages.

A medical device manufacturer has a duty to warn physicians of a danger arising from use of a product once that danger becomes known to the manufacturer. Therefore, a manufacturer has a continuing duty to adequately warn of defects in a product even after that product has left the control of the manufacturer.

Reasonable care is the degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

If Mrs. Jones has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the risks of the Eclipse filter she received.

Source: Ga. Code Ann., § 51-1-11(C); *Ford Motor Co. v. Reese*, 684 S.E.2d 279, 284 (Ga. App. 2009).

Defendants’ Objections:

Defendants object to this instruction as it is not a proper statement under Georgia law. Under Georgia law, whether premised on negligence or strict liability, Plaintiff must prove that “Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of its filter. *Shelton v. GALCO Int’l, Ltd.*, No. 3:16-CV-00033-TCB, 2017 WL 3597497 (N.D. Ga. July 19, 2017) (quoting *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)) (“[T]he duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of the product.”). Further, Plaintiff’s reliance on *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999) is misplaced. While the Georgia Courts acknowledge that there are

two separate causes of action, they also recognize that the same duty based elements apply to both strict liability and negligent failure to warn. J. Kennard Neal and Catherine Payne, *Ga. Products Liability Law* § 8:1 (4th ed. 2018) (“Georgia has traditionally recognized failure to warn claims arising both in negligence and in strict liability. [H]owever, Georgia courts make no distinction between the two, but apply the same duty concepts and the same tripartite test of foreseeability.”) (citations omitted); *Id.* at § 2:1 (“[I]n examining either type of claim, Georgia courts have consistently applied the same duty-based negligence analysis.”)

As to the duty owed to the physician, Defendants request that the same language used in the strict liability failure to warn be included.

Defendants’ proposed alternative is Defendants’ Proposed Instruction on negligent failure to warn.

Plaintiff’s Response:

Plaintiff does not agree to Bard’s proposed merger of the negligent failure to warn with the strict liability failure to warn instruction. Such theories of liability are separate and distinct, thus making the Booker instruction appropriate. *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999).

DAMAGES

It is the duty of the court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Jones on any or all of her claims, you must determine her damages. Mrs. Jones has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on speculation, guesswork or conjecture.

Damages are given as pay or compensation for injury done. Where one party is required to pay damages to another, the law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence that Mrs. Jones is entitled to recover damages, you should award to Mrs. Jones such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses, such as hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Mrs. Jones seeks to recover not only for her past medical expenses, but also for medical expenses that may be incurred in the future. If you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such future medical expenses, Mrs. Jones would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. Questions of whether, how much, and how long Mrs. Jones has suffered or will suffer are for you to decide.

Pain and suffering include mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering. In evaluating Mrs. Jones' pain and suffering, you may consider the following factors, if proven:

- (1) interference with normal living;
- (2) interference with enjoyment of life;
- (3) impairment of bodily health and vigor;
- (4) fear of extent of injury;

- (5) shock of impact;
- (6) actual pain and suffering, past and future;
- (7) mental anguish, past and future; and
- (8) the extent to which Mrs. Jones must limit activities.

If you find that Mrs. Jones' pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Mrs. Jones will endure. In making such an award, your standard should be your enlightened conscience as impartial jurors. You may take into consideration the fact that Mrs. Jones is receiving a present cash value award for damages not yet suffered.

Bard must take Mrs. Jones in whatever condition it finds her. A negligent actor must bear the risk that its liability will be increased by reason of the actual physical condition of the person toward whom its act is negligent. Thus, if you find that Mrs. Jones' injuries were increased by her existing physical condition, you may award damages for those increased injuries provided you find they were proximately caused by Bard.

Defendants' Objection:

Defendants object to the last paragraph as it is not conformed to the evidence in this case. There is no evidence or testimony that any actions of Bard caused or contributed to Ms. Jones' existing medical conditions.

Plaintiff's Response:

To the extent Bard is allowed to introduce evidence of Plaintiff's unrelated medical conditions or allegedly acting against medical advice, the limiting paragraph is important to clarify for the jury that the defendant takes the victim as it finds her. If Plaintiff's MIL Nos. 1-3 are granted, Plaintiff will agree to withdraw the last paragraph.

PLAINTIFF'S PROPOSED INSTRUCTION RE PUNITIVE DAMAGES

Members of the jury, you have decided that Mrs. Jones should be awarded punitive damages. In order to determine the amount of punitive damages, the parties have presented evidence and will now present brief arguments.

The measure of punitive damages is your enlightened conscience as an impartial jury. Any award you make should be both reasonable and just in light of your previous award of compensatory damages, the conduct and circumstances of Bard, and the purpose of punitive damages.

In considering the amount of punitive damages, you may consider the following factors:

- 1) the nature and reprehensibility of Bard's conduct;
- 2) the extent and duration of Bard's wrongdoing and the likelihood of its recurrence;
- 3) the intent of Bard in committing the wrong;
- 4) the profitability of Bard's wrongdoing;
- 5) the amount of compensatory damages you have previously awarded;
- 6) the financial circumstances, that is, the financial condition or the net worth of Bard.

In making an award of punitive damages, you should consider the degree of reprehensibility of Bard's wrongdoing. You should consider all of the evidence, both aggravating and mitigating, to decide how much punishment, penalty, or deterrence Bard's conduct deserves in the form of punitive damages. In assessing reprehensibility, you may consider whether:

- 1) the harm caused was physical, as opposed to economic;
- 2) the conduct showed an indifference to or a reckless disregard of the health or safety of others; and
- 3) the conduct involved repeated actions or was an isolated incident.

You may have heard evidence of other conduct and procedures of Bard. For the purpose of punitive damages, you may not consider evidence of any conduct of Bard that

is dissimilar to that which resulted in Mrs. Jones' injury – unless such dissimilar conduct was related to the specific harm suffered by Mrs. Jones in this case.

Defendants' Objections:

Defendants acknowledge that Plaintiff's proposed instruction is the same as the one that was given in *Booker*; however, Defendants object to this charge because it does not comply with the US Supreme Court decisions on punitive damages. See, *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996); *Dimaso v. Ford Motor Company, et. al.*, No. 99-A-6172-6, 2003 WL 22850075, at *1 (Ga. Super. 2003); *Hockensmith v. Ford Motor Co.*, No. 1:01-CV-3645G, 2003 WL 25639639, at *10 (N.D. Ga. Apr. 17, 2003). See also Georgia Suggested Pattern Jury Instructions, Vol. I: Civil Cases, No. 66.770-66.780 (5th ed. 2016).

Defendants' proposed alternative is Defendants' Proposed Instruction A regarding punitive damages.

Plaintiff's Response:

For the reasons stated in Plaintiff's response to Bard's new charge on punitive damages, Plaintiff maintains that the *Booker* instruction accurately stated the law and is appropriate for this case.

PLAINTIFF'S REQUESTED FDA LIMITING INSTRUCTION

The FDA's review of a medical device depends upon how the device is classified under FDA regulations.

Certain devices are reviewed under FDA's Pre-Market Approval (PMA) process, which approves products focusing on a device's "safety and efficacy."

The FDA's 510(k) process determines whether a device is "substantially equivalent" to another device already legally on the market., it does not evaluate devices for safety and efficacy.

Bard's IVC filters, including Doris Jones' Eclipse IVC filter, were not FDA approved through the PMA process, but were cleared by the FDA through its 510(k) process.

Defendants' Objections:

Defendants object to this instruction on the grounds that it is a comment on facts that should be testified to by witnesses or presented through exhibits. Defendants do not offer an alternative instruction as they do not believe that a statement on the facts or evidence is appropriate

Plaintiff's Response:

Plaintiff responds that this instruction is likely to be appropriate given the emphasis at trial on FDA activity with respect to filter clearance. In submitting this instruction, Plaintiff understands that the Court will evaluate the evidence at trial to determine whether such an instruction is necessary.

PLAINTIFF'S PROPOSED INSTRUCTION RE MANUFACTURER'S SCOPE OF KNOWLEDGE

**PRODUCTS LIABILITY – DEFECT DUE TO INADEQUATE WARNING;
MANUFACTURER HELD TO THE KNOWLEDGE AND SKILL OF AN EXPERT**

In cases such as the instant case, a manufacturer is held to the knowledge and skill of an expert. This is relevant in determining (1) whether the manufacturer knew or should have known of a danger in its product and (2) whether the manufacturer was negligent in failing to communicate this superior knowledge. The manufacturer's status as an expert means that at a minimum, it must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imported thereby.

Even more importantly, a manufacturer has a duty to test and inspect its product. The extent of research and experiment must be commensurate with the dangers involved. A product must not be made available without disclosures of these dangers that the application of reasonable foresight would reveal. Nor, may a manufacturer rely unquestioningly on others to sound such disclosure concerning a danger in this product. Rather, each manufacturer must bear the burden of showing that its own conduct was proportionate to the scope of its duty.

Borel v. Fibreboard Paper Prods., Corp., 493 F.2d 1076, 1080-1090 (5th Circuit);
The Corporation of Mercer University v. National Gypsum Co., et al., 1986 WL 12445 (M.D. Ga. 1986).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is not a proper statement of Georgia law. The cases cited by Plaintiff do not apply to this case. *Borel v. Fibreboard Paper Prods, Corp.* 493 F. 2d 1076 (1973) applies Texas law. Plaintiff cites no case that stands for this proposition under Georgia law. In addition, *The Corporation of Mercer University v. National Gypsum Co*, 1986 WL 12445 (M.D. Ga. 1986) is not applicable. It was a property damage claim over the removal of asbestos and does not stand for the proposition stated in the charge. The charge expands the duty of a manufacturer beyond what is required by Georgia law. The Court refused to give this instruction in *Booker*.

Defendants propose as alternative instruction their proposed instructions on strict liability and negligent failure to warn.

Plaintiff's Response:

The law is correctly stated as set forth in *Mercer, supra*. While *Mercer* was an asbestos case, it stands for the unremarkable and unsurprising proposition that

manufacturers of products should, at a minimum, be aware of the knowledge available in the scientific community concerning their products. *Id.* at *2.

PLAINTIFF'S PROPOSED INSTRUCTION RE SCOPE OF DUTY TO WARN

PRODUCTS LIABILITY – MANUFACTURER'S DUTY TO WARN

You must decide whether adequate efforts were made by Bard to communicate all risks that were known to Bard or reasonably should have been known to Bard to the physician who implanted the Eclipse Filter in Mrs. Jones, and whether the warning that Bard communicated was adequate. A warning is inadequate if it does not provide a complete disclosure of both the existence of the risk and the extent of the danger and the severity of any potential injury involved.

Chrysler Corp. v. Batten, 264 Ga. 723, 724 (1994);
Ford Motor Co. v. Stubblefield, 171 Ga. App. 331, 335 (1984);
Watkins v. Ford Motor Co., 190 F.3d 1213, 1220 (11th Cir. 1999);
Stapleton v. Kawasaki Heavy Indus., Inc., 608 F.2d 571, 573 (5th Cir. 1979);
White v. W.G.M. Safety Corp., 707 F. Supp. 544, 549 (S.D. Ga. 1988);
Bryant v. Hoffman-La Roche, Inc., 262 Ga. App. 401, 410 (2003);
Sands v. Kawasaki Motors Corp., 2009 WL 3152859, at *5 (S.D. Ga. Sept. 30, 2009).

Defendants' Objections:

Defendants object to this instruction on the grounds that it is not a proper statement of Georgia law and attempts to extend the duty to warn beyond what is required. It is also duplicative of the instruction on failure to warn and will confuse the jury. Further in a case involving a learned intermediary, the fact the risks were known in the medical community is a factor that should be considered by the jury. *See Wheat v. Sofamor, S.N.C.*, 46 F.Supp.2d 1351, 1363 (N.D.Ga.1999) and *Ellis. C.R. Bard, Inc.*, 311 F.3d 1272 (2002). The Court declined to give this instruction in *Booker*.

Defendants propose as alternative instructions their proposed instructions on strict liability and negligent failure to warn. If the Court is inclined to give this instruction in addition to those, Defendants propose as an alternative instruction:

You must decide whether adequate efforts were made by Bard to communicate the risks that were known to Bard or reasonably should have been known to Bard to the physician who implanted the Eclipse Filter in Ms. Jones, and whether the warning that Bard communicated was adequate. However, in making that determination you make take into account whether the risks were generally known by Dr. Avino and the medical community generally.

Plaintiff's Response:

The proposed instruction correctly states the law and simply advises the jury that a warning that is inadequate if it does not fully disclose the risks and the extent of the danger. Plaintiff does not object to a modification of the instruction to clarify that the warning must be to physicians, not patients, but believes this topic is adequately covered in other instructions.

**PLAINTIFF’S PROPOSED INSTRUCTION RE RISKS TO BE WARNED
ABOUT**

**PRODUCTS LIABILITY – DUTY TO WARN OF KNOWN DANGERS AND
DANGERS THAT SHOULD HAVE BEEN KNOWN**

In considering whether Bard violated its duty to warn, you may consider not only what dangers Bard knew at the time the product was sold, but also what Bard should have known at that time by the application of reasonable, developed human skill.

Bishop v. Farhat, 227 Ga. App. 201, 206 (1997).

Defendants’ Objections:

Defendants object to this instruction on the grounds that it is duplicative of the proposed instructions on strict liability and negligent failure to warn. This charge is a paraphrase from *Bishop v. Farhat*, which actually cites to *Chrysler Corp. v Batten*, 264 Ga. 723 (1994). The Georgia Pattern Instruction on strict liability failure to warn is likewise taken from *Batten*. Therefore, there is no need for an additional charge.

Plaintiff’s Response:

This instruction is helpful to the jury in understanding the contours of the failure to warn claim and merely instructs (accurately) on the law imposing the duty to warn on Bard.